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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,877	03/07/2002	Ragnhild Frank	10134.200-US	9961

25908 7590 04/10/2003

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EXAMINER

BELLAMY, TAMIKO D

ART UNIT PAPER NUMBER

2856

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,877

Applicant(s)

FRANK ET AL.

Examiner

Tamiko D. Bellamy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Preliminary amendment dated 03/07/02 has been received and entered. Claims 20, 21, and 23-26 have been canceled. Claims 1-19, and 22 are currently pending.

Claim Rejections - 35 USC § 112

2. Claim 15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim of a narrow numerical range, which falls within a broader range, in the same claim, renders the claim indefinite.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 6, 11-13, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Laine et al. (5,648,610).

With respect to claims 1-3, 17, Laine et al. discloses granulating powders or powder compounds (col. 1, line 32), acoustic emission was measured during the compaction of three different pharmaceutical auxiliary substances (col. 4, lines 17-19), a microphone 20 is used to detect acoustic emission (col. 5, lines 6-8), the signals are recorded using a frequency analyzer measuring frequencies in the range of 0-100 kHz, and the invention is applicable to all types of powders (col. 4, lines 11-12). Laine et al.

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does not specifically disclose the powder contains a biologically active compound; however, Laine et al. discloses the invention is applicable to all types of powders which inherently includes a powder containing a biologically active compound (col. 4, lines 11-12).

With respect to claim 6, Laine et al. discloses the acoustic emissions are recorded and transformed into a frequency spectrum by using Fast Fourier Transformation (col. 4, lines 21-24).

With respect to claims 11-13, Laine et al. discloses acoustic emission was measured during the compaction of three different pharmaceutical auxiliary substances: crystalline lactose monohydrate, microcrystalline cellulose, and maize starch (col. 4, lines 17-19). The pharmaceutical auxiliary substances are equivalent to a granulation composition that comprises an auxiliary granulation agent. It is well known in the art that lactose is use as a tablet binder.

With respect to claim 18, the acoustic signals were recorded at 5 kN intervals, for two minutes at a time (col. 5, lines 17-25).

With respect to claim 19, Laine et al. discloses granulating powders or powder compounds (col. 1, line 32), and extensive series of test compressions have been made with powder or powder compound in order to find the suitable compression pressure for the production process (col. 2, lines 9-12).

Claim Rejections - 35 USC § 103

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4, 5, 7-10, 14-16, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laine et al. (5,648,610).

With respect to claims 4 and 5, Laine et al. discloses a microphone 20 is used to detect acoustic emission (col. 5, lines 6-8). Laine et al. lacks the detail of the vibration detector sensor is a piezo-electric sensor, or an accelerometer. However, Laine et al. cites prior art makes use of a piezo-electric sensor. It is well known in the art to use a piezo-electric sensor or an accelerometer to detect vibrations. Therefore, it would have been obvious to one of ordinary skill in the art to provide Laine et al. with a piezo-electric sensor, or an accelerometer, so that the device can detect acoustic emissions.

With respect to claims 7 and 8, Laine et al. does not specifically disclose the power contains a biologically active compound in pure form; and the biologically active compound is selected from bio-catalysts, therapeutic agents, herbicides, pesticides and fungicides. However, Laine et al. discloses the invention is applicable to all types of powders that inherently include a powder containing a biologically active compound (col. 4, lines 11-12). Furthermore, Laine et al. discloses acoustic emission was measured during the compaction of three different pharmaceutical auxiliary substances (col. 4, lines 17-19). The use of pharmaceutical auxiliary substances includes therapeutic agents. It would have been obvious to one of ordinary skill in the art to provide Laine et al. with a

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power contains a biologically active compound in pure form and selected from therapeutic agent, so that the device can detect the amount of biologically active compound released from the granule of powder.

With respect to claims 9 and 10, Laine et al. lacks the detail of the biologically compound selected from proteins and peptides, and the biologically compound is an enzyme. Laine et al. discloses the invention is applicable to all types of powders that inherently include a powder containing a biologically active compound (col. 4, lines 11-12). It would have been obvious to one of ordinary skill in the art to provide Laine et al. with a power contains a biologically compound that is an enzyme and selected from proteins and peptides, so that the device can detect the amount of biologically active compound released from the granule of powder.

With respect to claims 14,16, and 22, Laine et al. discloses the purpose of granulation is to produce, from the powder, granules of the appropriate size, and to improve the flow and distribution accuracy of mass and reduce dusting for the compacted powder. (col. 1, line 28-37), Laine et al. lacks the detail of the granules being coated. It would have been obvious to one of ordinary skill in the art to provide Laine et al. with granules having a coating, so at to help aid in reducing dust produced from a powder compound.

With respect to claim 15, Laine et al. discloses the purpose of granulation is to produce, from the powder, granules of the appropriate size (col. 1, line 28-30). Laine et al. lacks the detail of the granules having an average size between 20-2000 μm , 100-1000 μm , or 200-800 μm . Where the range of article sizes disclosed in the prior art envelopes

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the recited range, and there is no showing of criticality of the recited range, such recited range would have been one of ordinary skill in the art. In re Reven, 390 F.2d 997, 156 USPQ 679 (CCPA 1968). It would have been obvious to one of ordinary skill in the art to provide Laine et al. with granules having an average size between 20-2000 μm to improve the flow and distribution accuracy of mass and reduce dusting for the compacted powder.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamiko D. Bellamy whose telephone number is (703) 305-4971. The examiner can normally be reached on Monday through Friday 8:30 AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (703) 305-4705. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1782.

Tamiko Bellamy

T.B.
April 7, 2003

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A handwritten signature in black ink, appearing to read "Hezron S. Williams", with a long horizontal line extending to the right.

HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800